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10/577,282

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Paul Bach-Y-Rita

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EXAMINER

SCHAETZLE, KENNEDY

ART UNIT

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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/577,282	<b>Applicant(s)</b> BACH-Y-RITA ET AL.	
	<b>Examiner</b> Kennedy J. Schaetzle	<b>Art Unit</b> 3766	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-34 is/are pending in the application.  
4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-27 and 33 is/are rejected.
- 7) ☐ Claim(s) 28-32 and 34 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 24 April 2006 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                                | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. ____. |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)                        | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____.  |

## **DETAILED ACTION**

### ***Drawings***

1. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the electrical stimulation embodiment (claims 3, 14 and 27); the thermal stimulation embodiment (claims 4, 15 and 28); the embodiment where the stimulators are not in direct or indirect physical contact with each other (claims 11 and 22) must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

3. Claims 1-11 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. The reference to the stimulators as being implanted in the skin is impermissible since the body is non-statutory. The examiner suggests amending the claim to incorporate the phrase, "...adapted to be implanted..." or the phrase, "...for implant" in order to functionally recite the relationship between the stimulators and the body.

***Claim Rejections - 35 USC § 112***

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 11 and 22 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

It is unclear what it means for the stimulators to be in neither direct nor indirect physical contact with each other. The applicants appear to only show an embodiment where the stimulators are affixed in a web to form an array (i.e., the stimulators are not in direct contact, but rather in indirect contact with each other through the fabric web such as discussed on page 6, first full paragraph of the present specification). It is therefore not understood how a stimulator can be both not in direct or indirect physical

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contact with each other. The examiner will assume the claim limitation pertains to stimulators that are not in direct physical contact with each other, but that are in indirect physical contact with each other, such as through a web material, or that the stimulators are physically distinct from one another.

***Claim Rejections - 35 USC § 102***

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

7. Claims 1-4, 8-15, 20-27 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Schouenborg (Pat. No. 5,449,378).

Regarding claims 1, 3, 12 and 14, Schouenborg discloses a tactile input system comprising multiple stimulators 7 implanted in the skin of a subject below the epidermis (see col. 5, lines 50- col. 6, line 21) in a closely spaced array (see Fig. 1 and col. 6, lines 22-40), wherein the stimulators or a portion thereof are independently configured to deliver a tactile stimulation (see col. 2, lines 44-53 and col. 6, lines 45-60).

Regarding claims 2 and 13, the tactile stimulators deliver mechanical stimulation to the body when pushed into the skin.

Regarding claims 4 and 15, the electrodes of Schouenborg are considered to be configured to deliver tactile thermal stimulation in that if one were to apply heat energy through the conductive electrical line 3, the conductive electrode/stimulator 7 would transmit the heat energy to the body. The applicants are not claiming a thermal

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transducer capable of generating or producing thermal energy, but merely a stimulator capable of imparting, transmitting or delivering perceptible thermal energy to the body. While a stimulator might be an example of a transducer, not all stimulators are necessarily transducers.

Regarding claims 9 and 20, note col. 5, lines 1-10 and col. 6, lines 14-21.

Regarding claims 10 and 21, element 1 is considered to constitute a movable diaphragm. Element 1 appears to be at least capable of being implanted due to the fact that it can be made of silicone rubber –a biocompatible material. Limitations regarding the location of apparatus with respect to the body fail to saliently distinguish over prior art apparatus that is at least capable of similar placement –regardless of intent.

Regarding claims 11 and 22, element 1 prevents the stimulators from being in direct contact with each other. Note also the comments made above in the rejection of said claims under 35 USC §112, 2nd paragraph.

Regarding method claim 23, information is conveyed to the brain of a subject when the stimulators are implanted in the skin and/or activated (i.e., the subject's brain senses that the device has penetrated the skin and/or has been electrically activated).

The rejection of method claims 24-27 parallels the rejection of similarly worded apparatus claims.

Regarding claim 33, the tactile feel of the stimulators penetrating the skin or electrically stimulating the body provides environmental information (i.e., by such sensations the subject can ascertain that the device has been placed on his/her body and/or has been activated).

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8. Claims 1, 3, 5, 7, 8, 11, 12, 14, 16, 18, 19 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by McConnell (Pat. No. 4,813,419).

Regarding claim 1 and related claims, McConnell discloses a tactile input system comprising implanted multiple stimulators (e.g., the left and right stimulators shown in Fig. 6), wherein the stimulators or a portion thereof are independently configured to deliver a tactile stimulation (by virtue of the fact that such a system applies a two-channel stereo signal derived from separate microphones). Concerning the limitation pertaining to implant in the skin of a subject below the epidermis in a closely spaced array, since the tactile sensory nerve targets are contained within the skin below the epidermal layer, the implant and electrodes would necessarily be placed at the claimed location. Furthermore, since the system of McConnell is intended for implant, it is at least considered capable of being placed in such a location. While statements of intended use (i.e., for placement in the skin below the epidermis in a closely spaced array) were considered, such statements fail to saliently distinguish over apparatus capable of similar placement. In addition, the relative and undefined phrase "closely spaced array" is subjective and thus open to interpretation. One can therefore consider stimulators located in the right and left wrists to be "closely spaced" when compared to stimulators placed at the bottom of the feet and head of the subject. The spacing of stimulators in an array also depends on how close the wrists are placed to one another.

Regarding claim 22, the stimulators located in separate wrists are considered to be not in direct physical contact with each other. Note also comments above concerning apparatus limitations directed to intended location of apparatus.

***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

11. Claims 7 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Schouenborg in view of Sevrain et al. (Pat. No. 4,926,879).

While Schouenborg does not explicitly discuss the use of a biocompatible coating, clearly any object intended to be inserted into the body must by design be biocompatible in order to prevent irritation, infection and corrosion. The coating of electrodes to either provide biocompatibility or further enhance their biocompatibility is old and well known in the medical art. Such a feature allows less expensive materials or materials that are not biocompatible to be used as the base material, with the coating providing the necessary biocompatibility and/or superior tissue/electrode interface



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characteristics. Sevrain et al. disclose a related tactile stimulator wherein the electrodes may be coated with a biocompatible, non-reactive material such as gold, titanium, platinum, etc.. Said materials have long been used in the medical arts due to their well known electrical and biocompatible properties. To therefore coat the electrodes of Schouenborg in order to take advantage of enhanced electrical and biocompatible characteristics, would have been considered a matter of obvious design by those of ordinary skill in the art.

12. Claims 6 and 17 are rejected under 35 U.S.C. 103(a) as being unpatentable over McConnell.

McConnell does not disclose the use of a light signal to wirelessly communicate with the stimulators. Official Notice is taken that it is old and well known in the medical art that transmission of wireless signals into the body may be done using light transmission through the skin. Such a means are simple in design, relatively free from interference, and allow non-invasive communication between an external communicator/programmer and a subcutaneous implant or detector. Clearly the choice of communication means is one of obvious design, with implant location, ambient noise, implant power requirements, etc., dictating the decision.

***Allowable Subject Matter***

13. Claims 28-32 and 34 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

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While the various limitations recited in the above mentioned claims are generally known in the art, there is no teaching of record to modify the base Schouenborg reference so as to incorporate these features.

Regarding application of McConnell to method claim 23, there is no teaching by McConnell to transmit a signal from a transmitter (i.e., singular) to multiple stimulators. In the embodiment shown in Fig. 6, one transmitter transmits to one stimulator in order to provide independent right and left channels.

### ***Conclusion***

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kennedy J. Schaetzle whose telephone number is 571 272-4954. The examiner can normally be reached on M-F from 9:30 -6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carl Layno can be reached on M-F at 571 272-4949. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kennedy J. Schaetzle/  
Primary Examiner, Art Unit 3766

KJS  
March 21, 2011